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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,573	07/11/2003	Jian Chen	P1381R1C1P4C1	8245

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,573	CHEN ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-60 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Currently, claims 1-60 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to an isolated nucleic acid, a vector containing same, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 435, subclass 69.1.

II. Claims 10-13, 16 in part, and 17-21, drawn to an isolated polypeptide, and a composition thereof, classified in class 530, subclass 350.

III. Claims 14, 15, 16 in part, and 17-21, drawn to an antibody to the polypeptide, a composition thereof, and an article comprising same, classified in class 530, subclass 387.9.

IV. Claims 16 in part, and 17-21, drawn to a composition of an agonist of the polypeptide, and an article comprising same, classification depending upon the chemical entity of the agonist.

V. Claims 16 in part, and 17-21, drawn to a composition of an antagonist of the polypeptide, and an article comprising same, classification depending upon the chemical entity of the antagonist.

VI. Claims 22 and 23 in part, drawn to a method of treating an immune related disorder using the polypeptide, or an agonist thereof, classified in class 514, subclass 2.

VII. Claims 22 and 23 in part, drawn to a method of treatment using an antagonist of the polypeptide, or an antibody to the polypeptide, classified in class 424, subclass 139.1.

VIII. Claim 24 and 26, drawn to a method for determining the presence of a polypeptide using an antibody, classified in class 435, subclass 7.1.

IX. Claim 25, drawn to a method of diagnosis by detecting the level of expression of a gene, classification depending upon the method steps.

X. Claims 27 and 30, drawn to a method of identifying a compound inhibiting or mimicking the *activity* of the polypeptide, classified in class 435, subclass 7.1.

XI. Claims 28 and 29, drawn to a method of identifying a compound inhibiting the *expression of a gene* encoding the polypeptide, classification depending upon the method steps.

XII. Claim 31, drawn to a method of stimulating the proliferation of T cells with a polypeptide or an agonist thereof, classified in class 435, subclass 7.1.

XIII. Claim 32, drawn to a method of inhibiting the proliferation of T cells with an antagonist of the polypeptide, classification depending upon the chemical entity of the agonist.

XIV. Claims 33 and 35, drawn to a method of decreasing the inflammatory cells in a mammal using a polypeptide or an agonist thereof, classified in class 424, subclass 85.2.

XV. Claims 34 and 35, drawn to a method of decreasing the inflammatory cells in a mammal using an antagonist of the polypeptide, classification depending upon the chemical entity of the antagonist.

XVI. Claims 36 and 38, drawn to a method for inhibiting angiogenesis in a mammal with an antibody to the polypeptide, or with an antagonist of the polypeptide, classified in class 424, subclass 139.1.

XVII. Claim 37, drawn to a method for stimulating angiogenesis in a mammal with a polypeptide or an agonist thereof, classified in class 514, subclass 2.

XVIII. Claims 39 and 40, drawn to a method of treating a degenerative cartilaginous disorder in a mammal using a polypeptide, or an agonist thereof, and a kit comprising same for the treatment, classified in class 424, subclass 85.2.

XIX. Claims 39 and 40, drawn to a method of treating a degenerative cartilaginous disorder in a mammal using an antagonist of the polypeptide, and a kit comprising same for the treatment, classification depending upon the chemical entity of the antagonist.

XX. Claims 41-48, drawn to a method of detecting a polypeptide with another polypeptide, classified in class 436, subclass 501.

XXI. Claims 49-54, drawn to a method of linking a bioactive molecule to a cell expressing the polypeptide, classified in class 435, subclass 7.21

XXII. Claims 55-58, drawn to a method of modulating a biological activity of a cell expressing the polypeptide with a polypeptide, classified in class 436, subclass 503.

XXIII. Claims 55-58, drawn to a method of modulating a biological activity of a cell expressing the polypeptide with an antibody, classified in class 435, subclass 7.1.

XXIV. Claims 59 and 60, drawn to a method for detecting the presence of tumor in a mammal, classification depending upon the method steps.

The inventions are distinct, each from the other because:

The nucleic acid of Invention I is related to the polypeptide of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecules and proteins are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The method of Invention I is related to the polypeptide of Invention II as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed may be isolated from their natural source or made by chemical peptide synthesis.

The nucleic acid of Invention I is distinct from and unrelated to the antibody, the agonist, and the antagonist of the polypeptide in Inventions III-V, respectively, because they are physically and functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention I is distinct

from and unrelated to the products of Inventions III-V because the products may be neither made by nor used in the method.

Invention I is distinct from and unrelated to Inventions VI-XXIV, wherein the nucleic acid of Invention I is neither made by nor used in the methods of Inventions VI-XXIV, and wherein each does not require the other.

The polypeptide of Invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

The polypeptide of Invention II is distinct from and unrelated to the agonist, and the antagonist of Inventions IV, and V, respectively, because they are physically and/or functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

The polypeptide of Invention II is related to the methods of Inventions VI, X, XII, XIV, XVII, XVIII and XX-XXII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for generating the antibody of Invention III.

Invention II is distinct from and unrelated to Inventions VII-IX, XI, XIII, XV, XVI, XIX, XXIII and XXIV, wherein the polypeptide of Invention II can be neither made by nor used in the methods of Inventions VII-IX, XI, XIII, XV, XVI, XIX, XXIII and XXIV, and wherein each does not require the other.

The antibody of Invention III is distinct from and unrelated to the agonist, and the antagonist of Inventions IV, and V, respectively, because they are physically and/or functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

The antibody of Invention III is related to the methods of Inventions VII, VIII, XVI and XXIII, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the purification of the polypeptide of Invention II.

Invention III is distinct from and unrelated to Inventions VI, IX-XV, XVII-XXII and XXIV, wherein the antibody of Invention III can be neither made by nor used in the methods of Inventions VI, IX-XV, XVII-XXII and XXIV, and wherein each does not require the other.

The agonist of Invention IV is distinct from and unrelated to the antagonist of Invention V, because they are physically and functionally distinct chemical entities, which share neither structure nor function. Also, neither is required for the manufacture of the other.

The agonist of Invention IV is related to the methods of Inventions VI, XII, XIV, XVII and XVIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for identifying a receptor for the polypeptide of Invention II.

Invention IV is distinct from and unrelated to Inventions VII-XI, XIII, XV, XVI and XIX-XXIV, wherein the agonist of Invention IV can be neither made by nor used in the methods of Inventions VII-XI, XIII, XV, XVI and XIX- XXIV, and wherein each does not require the other.

The antagonist of Invention V is related to the methods of Inventions VII, XIII, XV, XVI and XIX, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for identifying a receptor for the polypeptide of Invention II.

Invention V is distinct from and unrelated to Inventions VI, VIII-XII, XIV, XVII, XVIII and XX-XXIV, wherein the antagonist of Invention V can be neither made by nor used in the

methods of Inventions VI, VIII-XII, XIV, XVII, XVIII and XX-XXIV, and wherein each does not require the other.

Inventions VI-XXIV are drawn to independent methods, wherein each of the methods has different process steps, different active reagents, different starting and ending points, and is for a different purpose, such that they require separate searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, if any one of the groups I-XIII and XVIII-XXIVI above is elected, further restriction is required under 35 U.S.C. 121:

A. Elect one specific amino acid sequence with SEQ ID NO from SEQ ID NO:2, 4, 6, 8, 10, 12, 14, 16 and 18.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs represents a unique and separately patentable sequence, requiring a separate search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

In order to be fully responsive, Applicant must elect one from Groups I-XXIV, one from Group A, even though the requirement is traversed. Applicant is advised that neither I-XXIV nor A are species election requirements; rather, each of I-XXIV, and A is a restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dong Jiang

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Patent Examiner
AU1646
1/24/06